IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
EASTERN DIVISION

HEART TO HEART HOSPICE, INC. PLAINTIFF

VS. CIVIL ACTION NO. 1:07CV289-M-D

MICHAEL O. LEAVITT, SECRETARY OF
OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES DEFENDANT

CONSTITUTIONAL AND STATUTORY COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND FOR SUMS DUE UNDER THE MEDICARE ACT

Comes now the plaintiff, Heart to Heart Hospice, Inc., and files its Complaint for Declaratory and Injunctive Relief and for Sums Due Under the Medicare Act, and in support of same would state as follows, to-wit:

I. Introduction

1. Plaintiff Heart to Heart Hospice, Inc. is a Medicare certified hospice provider in Belmont, Mississippi. As a hospice provider, Heart to Heart Hospice provides hospice care to eligible terminally-ill Medicare patients and services to their families.

2. The Federal government pays hospice providers like Heart to Heart Hospice pursuant to a Medicare program established under Title XVIII of the Social Security Act (the "Medicare Act"). The Department of Health and Human Services ("HHS") administers the

hospice benefit and reimburses hospice providers on a per diem basis for services to its beneficiaries. However, aggregate annual reimbursements to hospices are subject to an aggregate annual provider cap (the "cap"). Any provider whose revenues from Medicare exceed its aggregate cap are subject to demands for repayment of the difference from Medicare.

3. On April 9, 2007, HHS made a demand for repayment to Heart to Heart Hospice in the amount of $1,592,213 based upon its calculations for the period from November 1, 2004 through October 31, 2005. On April 17, 2007, Heart to Heart Hospice filed a timely appeal of the cap determination with the Provider Reimbursement Review Board ("PRRB"), challenging the validity of the Federal regulation pursuant to which the cap was calculated. Then, because it appeared that the PRRB lacked jurisdiction to assess the validity of a regulation, Heart to Heart Hospice sought expedited judicial review of its appeal on August 16, 2007. By letter dated September 12, 2007, the PRRB granted Heart to Heart Hospice's expedited judicial review request finding that there are no material facts in dispute, that the amount in controversy exceeds $10,000, and that Heart to Heart Hospice's appeal involves principally a legal challenge to the validity of the regulation. When the PRRB makes such a ruling, a Medicare provider has 60 days from the date of receipt to file a civil action in Federal District Court. 42 U.S.C. §1395oo(f)(1).

4. Heart to Heart Hospice believes that Medicare regulation governing calculation of the cap, 42 C.F.R. § 418.309(b), is contrary to the plain language of section 1814(i)(2)(C) of the Medicare Act (codified at 42 U.S.C. § 1395f(i)(2)(C)), is arbitrary and capricious, and amounts to unlawful taking of private property for public use without just compensation in violation of the Fifth Amendment of the United States Constitution. Heart to Heart Hospice has been severely prejudiced by HHS' refusal to abide the Congressional mandate regarding the methodology for calculation of the cap.

5. Accordingly, by this action, Heart to Heart Hospice seeks a declaration and order that: (a) Medicare regulation 42 C.F.R. § 418.309(b) is invalid, (b) HHS' prior calculations of Heart to Heart Hospice cap amounts pursuant to 42 C.F.R. § 418.309(b) are invalid, and (c) HHS must return to Heart to Heart Hospice all sums paid by Heart to Heart Hospice pursuant to demands based upon such invalid calculations and other further relief as appropriate.

II. Jurisdiction and Venue

6. This action arises under the Medicare Act, 42 U.S.C. § 1395 et seq.

7. This Court has jurisdiction under 42 U.S.C. § 1395oo(f) and 28 U.S.C. 1331.

8. Venue lies in this judicial district pursuant to 42 U.S.C. § 1395oo(f)(1) because this is the judicial district in which Heart to Heart Hospice is located.

III. Parties

9. Heart to Heart Hospice provides hospice services to eligible Medicare patients in Mississippi, namely patients who are terminally ill and who have been certified by medical personnel to have less than a six month life expectancy. The address of Heart to Heart Hospice's corporate office is 278 Hwy 366 E., P.O. Box 875, Belmont, Mississippi 38827.

10. Defendant Michael O. Leavitt is the Secretary of the Department of Health and Human Services, the federal agency responsible for administration of the Medicare program.

IV. Statutory and Regulatory Background

A. Hospice Benefit Background

11. The hospice benefit started as an experiment in humane end-of-life care. In 1982, when Congress created the hospice benefit, two caps—or limits—were imposed. A lifetime cap limited each beneficiary to a maximum of 210 days of hospice care and a cap on providers limited the amount each hospice could bill Medicare in a single year.

12. Initially, 95 percent of patients choosing hospice care were beneficiaries diagnosed with cancer who had exhausted or grown weary of other treatment options. They stayed in hospice care for only days or weeks and few patients or providers ever exceeded their respective limits. As a result, few, if any, hospices ever encountered any cap issue.

13. By the early 1990s, hospice was widely recognized as superior end of life care, and proved highly effective at reducing expensive and often unwanted hospitalizations. At that time, however, 75 percent of Medicare beneficiaries with terminal illnesses—those not suffering from cancer—still did not have access to hospice services. Medicare required a physician to certify that a beneficiary had six months or less to live before referring them to hospice care and many physicians chose not to refer non-cancer patients to hospice because of the uncertainties inherent in life expectancy calculations.

14. Congress took steps to address this obvious barrier in 1998 with legislation that eliminated the cap on a beneficiary's right to receive hospice care provided that a physician continued to certify that the patient had a life expectancy of six months or less. Pursuant to these changes, the Medicare Act now provides unlimited hospice coverage for individual Medicare beneficiaries who are certified as terminally ill with a life expectancy of six months or less. Specifically, the Medicare Act now allows hospice care for "two periods of 90 days each and an unlimited number of subsequent periods of 60 days." Section 1812(a)(4) and (d) of the Medicare Act (codified at 42 U.S.C. § 1395d(d)(1)) (emphasis added). The statutory provisions setting the hospice provider cap were not amended to make them consistent with the statutory expansions in hospice coverage. This expansion is, however, reflected in the Medicare manuals. The Medicare Hospice Manual states, "[a]n individual may elect to receive Medicare coverage for an unlimited number of election periods of hospice care. The periods consist of two 90-day

periods, and an unlimited number of 60-day periods." CMS Pub. 21, Ch. 2, Sec. 200. The Medicare Benefit Policy Manual ("MBPM") further states:

> An individual (or his authorized representative) must elect hospice care to receive it. The first election is for a 90-day period. An individual may elect to receive Medicare coverage for an unlimited number of election periods of hospice care. The periods consist of two 90-day periods, and an unlimited number of 60-day periods. If the individual (or authorized representative) elects to receive hospice care, he or she must file an election statement with a particular hospice. Hospices obtain elections from the individual and forward them to the intermediary, which transmits them to the Common Working File (CWF) in electronic format. Once the initial election is processed, CWF maintains the beneficiary in hospice status until death or until an election termination is received.

MBPM, Ch. 9, Sec. 10.

15. Critically, at the same time the statute was expanded, HHS began developing objective standards to define non-cancer patient hospice eligibility so that physicians would have confidence in making terminal diagnoses. These objective standards seek to identify objective characteristics in ten distinct terminal illnesses that suggest an average six month life expectancy.

16. Today, more of America's terminally ill seniors are being given a hospice choice, and eligible beneficiaries are able to remain enrolled in hospice services until they pass away.

Non-cancer patients now have better access to care, making up more than 50 percent of hospice patients. Nearly half of all Medicare patients who pass on have received end of life hospice care.

17. With these statutory changes to hospice coverage, medically eligible beneficiaries are able to stay longer in hospice care. As a consequence, average length of stay is rising. But, notably, it remains below six months.

18. Hospice providers rendering covered services to eligible Medicare beneficiaries have begun exceeding the cap at an alarming rate. In 1997, virtually no hospice providers exceeded the cap. In 2005, hospices in 18 states exceeded their cap. These providers were asked to repay Medicare $160 million. That same year, 62 percent of hospice providers in Mississippi had cap overpayment issues and were assessed over $45 million in Medicare overpayments.

B. The Calculation of the Cap

19. Since inception, the Medicare Act has provided that total payments to a hospice provider in any fiscal year may not exceed an aggregate hospice provider cap, calculated as the product of the individual cap amount (adjusted annually for inflation) and the "number of Medicare beneficiaries" in a hospice program in an accounting year. Section § 1814(i)(2)(A) of the Medicare Act (codified at 42 U.S.C. § 1395f(i)(2)(A)). In 2005, the cap amount was $19,777.51 per beneficiary. In spite of statutory expansions of coverage, Congress has yet to change the provider cap in the statute in any way.

20. The Medicare Act specifically provides that the number of beneficiaries in an accounting year must be adjusted to reflect the time each such individual was provided hospice care in a previous or subsequent accounting year (42 U.S.C. § 1395f(i)(2)(C)):

> For the purposes of subparagraph (A), the "number of Medicare beneficiaries" in a hospice program in an accounting year is equal

> to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan or care established by another hospice program.
>
> (Emphasis added.)

21. In 1983, when HHS issued its proposed regulation to implement the hospice cap, it acknowledged:

> The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice.

48 Fed. Reg. 38,146, 38,158 (Aug. 22, 1983). HHS also acknowledged that "The requirements [of the statute] do not allow discretion in the computation method." Id.

22. However, HHS nonetheless declined to adopt the specific computation methodology mandated by Congress and instead chose to give providers credit for the cap only in the initial year of service, regardless whether the patient lived into another accounting year:

> With respect to the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting

> year in which the preponderance of the hospice care would be expected to be furnished rather than attempt to perform a proportional adjustment.

(Emphasis added.) 48 Fed. Reg., supra, at 38,158 (Aug. 22, 1983).

23. In so doing, HHS conceded that it was planning not to implement the plain language of the statute because it would be "difficult":

> Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted 'to reflect the proportion of the hospice care that each such individual was provided in a previous or subsequent accounting year . . . such an adjustment would be difficult in that the proportion of the hospice stay occurring in any given year would not be known until the patient dies or exhausted his or her hospice benefits. We believe the proposed alternative of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care will achieve the intent of the statute without being burdensome.

(Emphasis added.) 48 Fed. Reg., supra, at 38,158 (Aug. 22, 1983).

24. Notably, however, when it came to implementing the companion statutory requirement that the cap be apportioned among different hospices if two or more provided services to a specific patient, Medicare regulations required such calculations:

> When a beneficiary elects to receive hospice benefits from two different hospices, we are proposing a proportional application of the cap amount.

. . .

> We are aware that this type of apportioning of the beneficiary's stay may result in the inclusion of a beneficiary in the calculation of the cap for a reporting period other than the period for which the services were furnished, since it is necessary that the beneficiary die or exhaust his or her benefits before the percentage can be determined. However, we believe that this proposal is the most equitable means of implementing the statutory directive to adjust the cap amount to reflect the proportion of care furnished under a plan of care established by another hospice program.

(Emphasis added.) 48 Fed. Reg., supra, at 38,158 (Aug. 22, 1983). In short, HHS demonstrated through its own conduct that apportionment of the cap across years was indeed possible.

25. In December 1983, HHS issued its final hospice reimbursement regulation, including the provision allocating the hospice cap amount for a beneficiary only to the initial year in which the patient elected hospice care. The regulation provides:

> Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes –
>
> (1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have

> filed an election to receive hospice care, in accordance with § 418.24 from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).
>
> (2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represent the portion of a patient's total stay in all hospices that was spent in that hospice. . .

42 C.F.R. § 418.309(b)(1) and (2) (emphasis added).

26. To attempt to ameliorate the negative effects of the departure from the Congressional mandate to allocate the cap across years of care, HHS shifted the initial reporting year for "first election" of care from the standard Medicare fiscal year (November 1 through October 31) to an earlier time frame (September 28 to following September 27). Thus, if a patient was admitted September 27, 2005, such patient's cap allocation would be entirely to fiscal year 2005; however, if the same patient was admitted September 28, 2005, such patient's cap allocation would be entirely to fiscal year 2006. Heart to Heart Hospice alleges that this shift is insufficient to ameliorate the prejudice to hospice providers by HHS' failure to allocate cap allowances proportionally to the years in which services are actually rendered.

27. HHS' allocation of the cap amount only to the first reporting period in which the beneficiary elects the hospice benefit results in the assignment of the entire cap amount to the first reporting period even if most of the hospice care for that patient is rendered in a subsequent period. Thus, unused cap amounts in one fiscal year are "trapped" in the prior year, regardless

whether the beneficiary continues to receive care in subsequent years. The failure to allocate the cap across years of care results in an understated aggregate hospice cap.

28. HHS' failure to follow the Congressional mandate to allocate the cap proportionately across years of care subjects hospice providers to improper repayment demands for services properly rendered.

V. Facts Specific to This Case

29. Heart to Heart Hospice received its license as a hospice provider in Mississippi on June 20, 2001, and since that time has served almost 1000 patients and their families throughout the state.

30. Heart to Heart operated under its cap in 2001 and 2002, but because of the cap regulation which traps cap room in prior years, on April 9, 2007, HHS sent Heart to Heart Hospice demand for repayment of $1,592,213 for exceeding its fiscal year 2005 cap. If HHS had followed the Congressional mandate to allocate cap room across years of service, Heart to Heart Hospice asserts that its cap liability for fiscal year 2005 would have been materially reduced or even eliminated entirely. As a result, Heart to Heart Hospice has suffered material prejudice from Medicare's failure to follow the Congressional mandated allocation of cap allowances across years of service.

VI. Assignment of Errors

31. HHS' regulation specifying the calculation of the hospice cap, specifically 42 C.F.R. § 418.309(b)(1), is contrary to the Medicare Act (specifically 42 U.S.C. § 1395f(i)(2)(C)), is arbitrary and capricious, and amounts to an unlawful taking of private property for public use without just compensation in violation of the Fifth Amendment of the Unties States Constitution.

VII. Relief Requested

Heart to Heart Hospice respectfully requests the following relief:

1. A declaration that HHS' regulation regarding the calculation of hospice cap, specifically 42 C.F.R. § 418.309(b)(1), is invalid.

2. If this Court should find that 42 C.F.R §418.309(b)(1) is a valid exercise of authority under 42 U.S.C. § 1395f(i)(2)(C), a declaration that this statutory provision is invalid under the Fifth Amendment to the Constitution that prohibits the taking of private property for public use without just compensation.

3. A declaration that HHS' prior calculation of Heart to Heart Hospice's cap liability for fiscal year 2005 is invalid.

4. An order requiring HHS to return to Heart to Heart Hospice, with interest, all monies Heart to Heart Hospice has paid towards repayment of the alleged 2005 overpayment.

5. Pending resolution of this matter, a preliminary injunction enjoining HHS from continuing to demand repayment of the alleged 2005 overpayment and from calculating subsequent fiscal year alleged overpayments relating to Heart to Heart Hospice pursuant to the current version of 42 C.F.R. § 418.309(b)(1).

6. An order requiring defendant to pay legal fees and costs of suit incurred by plaintiff.

7. Such other and further relief as the Court may consider appropriate.

Respectfully Submitted,

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